



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY - 7 1999

1556 '99 MAY 10 P2:32

The Honorable Nancy L. Johnson  
House of Representatives  
Washington, D.C. 20515-0706

Dear Ms. Johnson:

Thank you for your letter of March 30, 1999, on behalf of your constituent, Dr. Allen M. Schoen of Sherman, Connecticut, regarding proposed new Food and Drug Administration (FDA) regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body.

FDA published this proposed rule in the Federal Register on April 29, 1998. The comment period closed on August 27, 1998; however, FDA extended the comment period until September 28, 1998. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

Your comments have been forwarded to the docket for this issue. While the Agency is under no legal obligation to consider comments received after the comment period, we do try to accommodate all comments as time and resources permit.

We would like to clarify one aspect of the proposed rule referred to in your letter. You state that under the FDA's proposal, pregnancy, menopause, and aging could be defined as interruptions of the normal structure or function of the body, and thus any claim made for alleviating symptoms of these states would be a disease claim. However, the proposal is consistent with your view that these states are not diseases. It proposes to cover as disease claims only claims to treat diseases associated with these conditions, e.g., toxemia of pregnancy, or Alzheimer's disease. In the proposed rule, the Agency states that:

Certain natural states, such as pregnancy, aging, or the menstrual cycle, that are themselves not "diseases," are sometimes associated with abnormalities that are characterized by a specific set of signs or symptoms, and

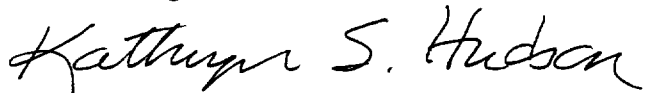
98N-0044


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thus meet the definition of disease. Under proposed 21 CFR 101.93(g)(2)(iii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body, such as toxemia of pregnancy, premenstrual syndrome, or abnormalities associated with aging such as presbyopia, decreased sexual function, Alzheimer's disease, or hot flashes. Claims that did not refer to a recognizable abnormality resulting from a natural state or to its signs or symptoms (e.g., "for men over 50 years old," and "to meet nutritional needs during pregnancy") would not be disease claims under this criterion (63 FR 23627).

Enclosed is information that may be of interest to you. We trust this information responds to your concerns. If we may be of any further assistance, please contact us.

Sincerely,



 Melinda K. Plaisier  
Interim Associate Commissioner  
for Legislative Affairs

Enclosure

"April 24, 1998 HHS News release"

cc: Dockets Management Branch  
(Docket No. 98N-0044)

NANCY L. JOHNSON  
6TH DISTRICT, CONNECTICUT

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March 30, 1999

Ms. Diane Thompson  
Legislative Affairs  
Food and Drug Administration  
5600 Fishers Lane  
Room 1555  
Rockville, MD 20857

Dear Ms. Thompson:

I am forwarding to your attention a letter that I received from one of my constituents concerning the FDA's notice of proposed rulemaking regarding dietary supplements. I would appreciate your attention to my constituent's concerns. If you can provide any supplemental information that would be helpful for me to use to respond to my constituent, I would appreciate that, as well. If you have questions about this letter, please contact Suanna Bruinooge in my Washington office at (202)225-4476.

Very truly yours,



Nancy L. Johnson  
Member of Congress

NLJ:sb  
enclosure

No 99-2354



**Allen M. Schoen, D.V.M., M.S.**  
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The Honorable Nancy L. Johnson  
Representative in Congress  
New Britain, CT  
Fax: 860-827-9009  
March 4, 1999

Dear Representative Johnson:

I am writing to notify you that FDA proposed rulemaking on structure/function claims, 21 CFR Part 101/Docket #98N-0044, is totally unacceptable to me as an American consumer of dietary supplements. Any final rule must reflect the true meaning and intent, mandated by Congress, of the Dietary Supplement Health and Education Act (DSHEA).

I support the FDA's effort to fully implement DSHEA as intended by Congress, however, I strongly object to the proposed regulations which:

- 1) limit my access to (scientific) information about dietary supplements and health, and
- 2) redefine disease restricting my ability to focus on preventive care and wellness.


It is extremely important to preserve Section 6 of DSHEA to allow for a robust flow of valuable health information in the marketplace.

I want free access to available information about dietary supplements and health, and I want FDA to withdraw its proposal to redefine disease in a way that limits such health information.

DSHEA allows products to make structure/function claims on the product labels. Redefining disease to nullify that part of DSHEA must be withdrawn.

I have written a letter of protest to the FDA directly and would like to ask you, Representative Johnson, to support the protest whenever you can. Thank you very much.

Sincerely,

  
Allen M. Schoen, D.V.M., M.S.  
Sherman, CT 06784